MERCK / Schering-Plough Pharmaceuticals

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AC-09-40

April 9, 2007

Roger Citron, R.Ph.
Montana Department of Public Health
and Human Services
1400 Broadway
P.O. Box 202951
Helena, MT 596202951

Dear Mr. Citron:

Our Senior NAE Representative, Elaine Zompolas, has referred your request for information regarding ZETIA (ezetimibe). Your inquiry concerned the indications for the use of ZETIA.

*Primary Hypercholesterolemia*
ZETIA, administered alone or with an HMG-CoA reductase inhibitor, is indicated as adjunctive therapy to diet for the reduction of elevated total-C, LDL-C, Apo B in patients with primary (heterozygous familial and non-familial) hypercholesterolemia.

*Homozygous Familial Hypercholesterolemia (HoFH)*
The combination of ZETIA and atorvastatin or simvastatin, is indicated for the reduction of elevated total-C and LDL-C levels in patients with HoFH, as an adjunct to other lipid-lowering treatments (e.g., LDL apheresis) or if such treatments are unavailable.

*Combination Therapy with Fenofibrate*
ZETIA, administered in combination with fenofibrate, is indicated as adjunctive therapy to diet for the reduction of elevated total-C, LDL-C, Apo B, and non-HDL-C in patients with mixed hyperlipidemia.

*Homozygous Sitosterolemia*
ZETIA is indicated as adjunctive therapy for the reduction of elevated sitosterol and campesterol levels in patients with homozygous familial sitosterolemia.

Therapy with lipid-altering agents should be a component of multiple risk-factor intervention in individuals at increased risk for atherosclerotic vascular disease due to hypercholesterolemia. Lipid-altering agents should be used in addition to an appropriate diet (including restriction of saturated fat and cholesterol) and when the response to diet and other non-pharmacological measures has been inadequate. (See NCEP Adult Treatment Panel (ATP) III Guidelines, summarized in Table 7 of the prescribing information)

Prior to initiating therapy with ZETIA, secondary causes for dyslipidemia (i.e., diabetes, hypothyroidism, obstructive liver disease, chronic renal failure, and drugs that increase LDL-C and decrease HDL-C [progestins, anabolic steroids, and corticosteroids]), should be excluded or, if appropriate, treated. A lipid profile should be performed to measure total-C, LDL-C, HDL-C and TG. For TG levels >400 mg/dL (>4.5 mmol/L), LDL-C concentrations should be determined by ultracentrifugation.

At the time of hospitalization for an acute coronary event, lipid measures should be taken on admission or within 24 hours. These values can guide the physician on initiation of LDL-lowering therapy before or at discharge.

The above information is supplied to you as a professional service in response to your specific request. Merck/Schering-Plough Pharmaceuticals does not recommend the use of its products in any manner other than as described in the prescribing information. Enclosed for your convenience is prescribing information for ZETIA.

Sincerely,

Ruth Stolz, MD

Ruth Stolz, M.D.
Director
Medical Services

Enclosure: Circulars